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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,672	08/31/2001	Victor E. Vandell	P 0282906	7805
909	7590	09/25/2006	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN, LLP			LAMM, MARINA	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1617

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,672

Applicant(s)

VANDELL, VICTOR E.

Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-18,20-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-18, 20-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/8/06 has been entered.

2. Claims pending are 1, 2, 4-18, 20-22 and 24-28. Claims 3, 19 and 23 have been cancelled. Claims 1, 20-22 and 24 have been amended. Claims 26-28 are new.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 4-18, 21 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 4,052,513) in view of Smith (US 5,874,074) and further in view of Castillo (US 5,993,836), all of record.

Kaplan teaches topical oil-in-water emulsions containing, in an oil phase, 0.5-15% of benzocaine solubilized in ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60; Example I. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties to the compositions. See col. 1, lines 30-44, 56-60. The compositions of Kaplan may contain polyethylene glycol,

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polyethylene glycol esters having MW of 200-600, thickeners such as xanthan gum, viscosity control agents such as paraffin and other cosmetic materials. See col. 2. The reference does not teach copolymers and plant oils of the instant claims. However, Smith teaches using PVP/hexadecane copolymer (Ganex V-216) as well as other PVP copolymers as barrier polymers "to form an occlusive or semi-occlusive film-like barrier on the surface of the skin to prevent evaporative loss of moisture from the skin, and protect the skin against environmental irritants" in topical formulations. See col. 4, lines 5-28. Further, the compositions of Smith may contain 0.05-1.5% of floral oils as fragrances "for cosmetic purposes." See col. 6, lines 35-48. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ PVP copolymers such as PVP/hexadecane copolymer. One having ordinary skill in the art would have been motivated to do this to obtain an occlusive or semi-occlusive film-like barrier on the surface of the skin to prevent evaporative loss of moisture from the skin, and protect the skin against environmental irritants as suggested by Smith. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ floral oils. One having ordinary skill in the art would have been motivated to do this to obtain fragrant effect as suggested by Smith. Neither reference teaches anhydrous compositions of the instant claims. However, Castillo teaches topical, transdermal anesthetic compositions comprising topical anesthetics incorporated within a lipophilic base. See Abstract.

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Castillo teaches that "by using a lipophilic vehicle rather than an oil-in-water delivery system, the formulation is markedly improved in stability". See col. 3, lines 62-64.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan in view of Smith such that to employ anhydrous lipophilic carrier instead of oil-in-water delivery system. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the formulation as suggested by Castillo.

5. Claims 20, 22, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 6,461,644) in view of Smith (US 5,874,074), both of record.

Jackson et al. teach anesthetizing polymer systems comprising a hydrophobic polymer (e.g. polyvinyl chloride, "PVC"), a topical anesthetic such as lidocaine base, prilocaine base and/or tetracaine, and a solubilizer for the topical anesthetic (e.g. isopropyl alcohol). See Abstract; col. 15, lines 50-62; Examples. Jackson et al. teach that lidocaine base and prilocaine base form an oily liquid mixture. See col. 15, lines 50-55. The delivery systems of Jackson et al. may also include fatty alcohols such as lauryl alcohol or oleyl alcohol. See col. 15, line 49; col. 16, lines 33-37; col. 21, Example 9. The anesthetizing polymer systems of Jackson et al. may be used as transdermal patches for providing an anesthetizing effect for hair removal procedures such as laser, waxing or electrolysis. See col. 20, Example 6; col. 31, lines 34-42. Jackson et al. teach applying lidocaine and polymer-containing transdermal patch

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(layer) to the site to be treated, leaving it on for a sufficient time to produce an anesthetizing effect, and then removing the patch (layer) from the skin. See col. 20, Example 6. Jackson et al. applied as above. With respect to Claim 20, Jackson et al. does not explicitly teach applying the anesthetizing polymer patches (layers) to the scalp. However, the anesthetizing method of Jackson et al. is suitable for removing hair from the skin by laser treatment, waxing or electrolysis, as discussed above. One skilled in the art would reasonable expect that the method of Jackson et al. is suitable for the hair removal from any part of the body, including scalp. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to modify the anesthetizing method of Jackson et al. such that to use it for hair removal from the scalp. One having ordinary skill in the art would have been motivated to do this because the method produces a sufficient block to withstand the treatment without pain, as suggested by Jackson et al. (see Examples). The Jackson et al. reference does not teach the claimed plant extract oil. However, Smith teach using floral oils as fragrances "for cosmetic purposes" in his topical anesthetic compositions. See col. 6, lines 35-48. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Jackson et al. such that to employ floral oils for their art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain fragrancng effect as suggested by Smith.

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6. Claims 20, 22, 24-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo (US 5,993,836) in view of Kaplan (US 4,052,513) and Smith (US 5,874,074), all of record.

Castillo teaches topical, transdermal anesthetic compositions comprising topical anesthetics incorporated within a lipophilic base. See Abstract. As lipophilic material, a mineral oil thickened with polyethylene can be used. See col. 5, lines 31-42. The topical anesthetic compositions of Castillo are applied to the skin of a patient and the compositions are left on the skin for 30-45 minutes or longer for the anesthetic to take effect. The Castillo reference does not teach the solubilizer and plant extract oil of the instant claims. However, Kaplan teaches topical compositions containing, in an oil phase, 0.5-15% of benzocaine solubilized in ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60; Example I. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties as well as improved stability to the compositions. See col. 1, lines 30-44, 56-60. Further, Smith teach using floral oils as fragrances "for cosmetic purposes" in his topical anesthetic compositions. See col. 6, lines 35-48. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Castillo such that to employ ester solubilizers for anesthetic agents. One having ordinary skill in the art would have been motivated to do this to obtain beneficial emollient properties as well as improved stability of the formulation as suggested by Kaplan. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made

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to modify the compositions of Castillo such that to employ floral oils for their art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain fragrancng effect as suggested by Smith. With respect to the claimed step of applying the composition to the scalp (vs. skin), the recitation of scalp does not patentably distinguish the instantly claimed method from that taught in the prior art because (1) scalp is skin and (2) it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the composition and method of Castello on any part of the body covered with skin, including scalp, for obtaining desensitizing and anesthetic effect. With respect to Claim 22, which recites the step of removing the composition from the hairy area of the scalp, the reference is silent about it. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the anesthetic composition from the skin once the effect is achieved and/or the cosmetic procedure is finished, so that the skin does not feel and look greasy.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments with respect to claims 1, 2, 4-18, 20-22 and 24-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


8. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
9/16/06


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